



# What Does it Mean to Employ RE-AIM?

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Co-Authors: Rodger S. Kessler, Ph.D; E. Peyton Purcell, MPH; Lisa M. Klesges, Ph.D;  
Russell E. Glasgow, Ph.D; C.J. Peek, Ph.D; Rachel M. Benkeser, MSPH

# Overview and Purpose

Lisa M. Klesges, PhD

Dean, School of Public Health

Professor of Epidemiology & Social and Behavioral Sciences

University of Memphis

# Overview

- Why is incomplete use of the RE-AIM or other program evaluation frameworks problematic?
- How are researchers proposing to evaluate outcomes to support translation and understand external validity?
- What evaluation measures are key to producing relevant research evidence?
- What are emerging issues?

# Background

- RE-AIM designed to support consistent reporting of interventions in context of external validity dimensions that could estimate population impact (RE-AIM framework: Glasgow, Vogt, Boles, 1999)
- Previously applied to systematic literature reviews on health promotion in different settings
- Evaluate relative merits of programs to enhance comparisons and decisions about “real world” impact (Glasgow, et al., 2006)
- Used to help plan programs and improve translation in “real-world” settings (Klesges, et al, 2005; Jilcott et al, 2007; King et al., 2010)
- Over 180 published studies report using the RE-AIM model

# RE-AIM Evaluation Model

## Reach (Individual Level)

- What percent of potentially eligible participants a) were excluded, b) took part and c) how representative were they?

## Efficacy or Effectiveness (Individual Level)

- What impact did intervention have on a) all participants who began the program; b) on process intermediate, and primary outcomes; and c) on both positive and negative (unintended) outcomes?

## Adoption (Setting Level)

- What percent of settings and intervention agents within settings (e.g., schools/educators, medical offices/physicians) a) were excluded, b) participated and c) how representative were they?

# RE-AIM Evaluation Model Cont.

## Implementation (Setting/agent Level)

- To what extent were intervention components delivered as intended? Did they vary by different (non-research) staff members in applied settings? What were costs?

## Maintenance (Individual Level)

- a) What were long-term effects (6-12 mo after intervention)? b) What was the attrition rate, c) Were drop-outs representative?

## Maintenance/Sustainability (Setting Level)

- a) To what extent were different intervention components continued or institutionalized? b) How was the original program modified?

# RE-AIM Fidelity

- Increasing number of grant applications propose to use the RE-AIM model for evaluation
- Incomplete or incorrect implementation of the evaluation model:
  - Variability in the number of elements proposed
  - Incorrect definitions of the key elements: Reach, Adoption, Effectiveness, Implementation, and Maintenance
  - Measures that do not “map” to definitions
  - Too few measures within elements to gain context of external validity and population impact

# Problems with Incomplete Use

- Creates confusion on ideal versus reduced models that could be replicated
- Hampers potential to conduct systematic reviews
- Limits practitioners ability to determine if a program is relevant to their particular setting (patients, resources, staff, measures, etc.)
- Incomplete comparisons between programs in evaluating effectiveness and public health impact
- Policy makers thwarted in defining a “standard” framework for decision-making and knowledge exchange



# Purposes of This Paper

- Define further elements of a fully “employed” model of the RE-AIM framework
  - what is essential for planning, evaluation, and reporting?
- New application in systematic review of *proposals* (vs. review of publications)
- Describe the extent that RE-AIM was applied in selected NIH proposals
- Offer recommendations for fidelity of evaluation models in general future applications of RE-AIM

# Methods and Results

Peyton Purcell, MPH, CPH  
Division of cancer Control and Population  
Sciences  
National Cancer Institute

# Research Methods

- Paradigm Case Framework (Peek 2011)
  - Identification of paradigmatic cases

*\*Definition of "Fully Developed Use" used in reported analysis.*

Reach
<b>Paradigm Case – Reach:</b> Grant/Journal/Activity includes: <ul style="list-style-type: none"><li>A. Exclusion Criteria (% excluded or characteristics);</li><li>B. Percent individuals who participate, based on valid denominator (not of volunteers who indicate interest);</li><li>C. Characteristics of participants compared to non-participants or to target population;</li><li>D. Use of qualitative methods to understand reach and/or recruitment</li></ul>
<b>"Fully Developed Use"</b> (a combination of elements that counts as genuine RE-AIM even if not every element in the paradigm case is included) - Reach: Grant/Journal/Activity includes: <ul style="list-style-type: none"><li>1. (B) and (C) <u>and</u> at least one other item (A or D) *</li></ul>

# Grant Analysis

- Study Selection
  - Trans NIH D&I Research in Health PAR (PAR-10-038 (R01); PAR-10-039 (R03); PAR-10-040 (R21))
  - 2005 - May, 2011
    - 253 applications
      - 42 (16.6%) mention RE-AIM
        - » 33 R01, 8 R21, 1 R03



# Applications by Setting and Topic

Study Topic	# of Proposals
Obesity/Physical Activity	8
Colorectal Cancer	7
Mental Health/Dementia	5
Tobacco/Drug/Alcohol	5
Breast Cancer/ Cervical Cancer	4
Cancer Control (Broad)	3
Systems Change	2
Other (CVD, Sun Safety, Bone health, Dental, HIV, Fall Prevention, Hearing impairment)	8

Study Setting	# of Proposals
Clinic/Health System	19 <sup>a</sup>
Community Based Organizations	7
Web-based/Online/Kiosk	6
Schools/After School Settings	3
Church/Faith-based Organization	3
Health/County Health Department	2
Workplace	2 <sup>a</sup>
Telephone Intervention	2
<sup>a</sup> This includes an online/web-based intervention delivered in this setting	

# Grant Analysis Continued

- Data Abstraction and Coding:
  - 31 specific items across five RE-AIM elements coded for inclusion:
    - Included (Yes/No)
    - Inappropriate Use
    - Not Applicable
  - Coded by two NCI staff members
    - Agreement assessed throughout process (average 89%)

# REACH RESULTS

RE-AIM Dimension and Items	Average Inclusion (%)
Reach	68.1
Exclusion Criteria (% excluded or characteristics)	88.9
Percent individuals who participate, based on valid denominator (not of volunteers who indicate interest)	80.6
Characteristics of participants compared to non-participants or to target population	66.7
Use of qualitative methods to understand reach and/or recruitment	36.1



# EFFECTIVENESS RESULTS

RE-AIM Dimension and Items	Average Inclusion (%)
Effectiveness	78.1
Measure of <u>primary outcome</u> (with or w/o comparison to a public health goal)	100.0
Measure of <u>broader</u> outcomes (e.g., measure of QoL or potential negative outcome) or use of multiple criteria	86.8
Measure of robustness across subgroups (e.g. moderation analyses)	81.6
Measure of <u>short-term attrition</u> (%) and <u>differential rates</u> by patient characteristics or treatment condition	60.0
Use of qualitative methods/data to understand outcomes	60.5



# ADOPTION RESULTS

RE-AIM Dimension and Items	Average Inclusion (%)
Adoption - Setting Level	74.7
Setting Exclusions (% or reasons)	75.0
Percent of settings approached that participate	91.7
Characteristics of settings participating (both comparison and intervention) compared to either: non participants or some relevant resource data	59.5
Use of qualitative methods to understand adoption at setting level	73.0
Adoption - Staff Level	44.7
Staff Exclusions (% or reasons)	40.0
Percent of staff invited that participate	48.5
Characteristics of staff participants vs. non participating staff or typical staff	31.3
Use of qualitative methods to understand staff participation	59.4

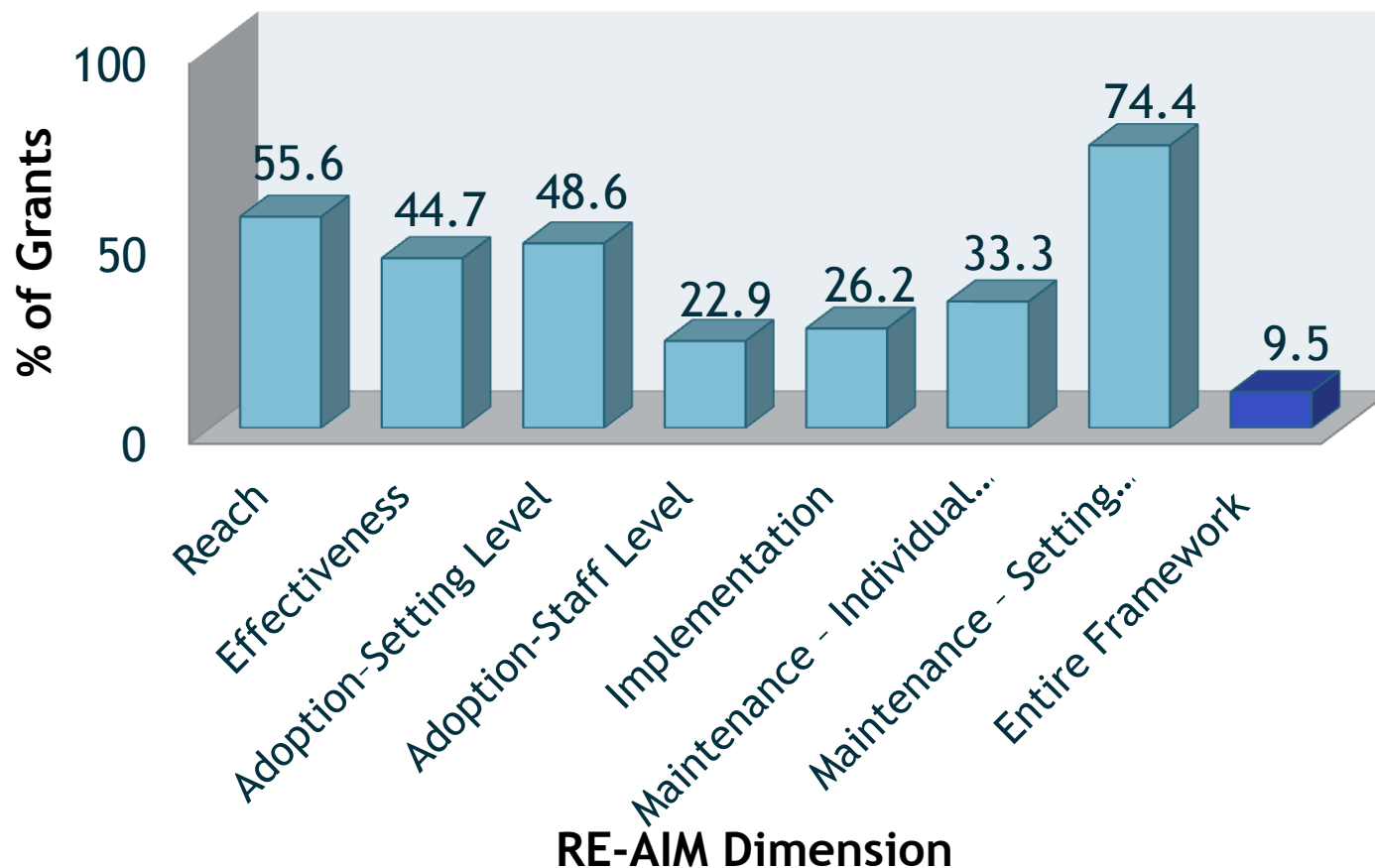
# IMPLEMENTATION RESULTS

RE-AIM Dimension and Items	Average Inclusion (%)
Implementation	66.3
Percent of perfect delivery or calls completed, etc.(e.g., fidelity)	85.4
Adaptations made to intervention during study	48.8
Cost of intervention (time or money)	58.5
Consistency of implementation across staff/time/settings/subgroups (not about differential outcomes, but process)	61.0
Use of qualitative methods to understand implementation	78.0

# MAINTENANCE RESULTS

RE-AIM Dimension and Items	Average Inclusion (%)
Maintenance - Individual Level	59.4
Measure of primary outcome (with or w/o comparison to a public health goal) at $\geq 6$ mo follow-up after final treatment contact	77.8
Measure of broader outcomes (e.g., measure of QoL or potential negative outcome) or use of multiple criteria at follow-up	60.6
Robustness data - something about subgroup effects over the long-term	57.1
Measure of long-term attrition (%) and differential rates by patient characteristics or treatment condition	45.7
Use of qualitative methods data to understand long -term effects	55.6
Maintenance- Setting Level	73.1
If program is still ongoing at $\geq 6$ month post study funding	82.1
If and how program was adapted long-term (which elements retained AFTER program completed)	53.8
Some measure/discussion of alignment to organization mission or sustainability of business model	74.4
Use of qualitative methods data to understand setting level institutionalization	82.1

# Figure 1. Percent of Grants with Fully Developed Use of RE-AIM Dimensions



# Emerging Issues and Discussion

Rodger Kessler Ph.D. ABPP  
Assistant Professor  
University of Vermont College of Medicine  
Collaborative Care Research Network  
National Research Network



# Variable implementation of the RE-AIM model across the five key dimensions

- 100% measures of effectiveness; (86%) multiple measures of effectiveness; broader outcomes such as unintended consequences or quality of life infrequently proposed
- 75% proposed estimates of the percent of target settings that were excluded
- Reach addressed more frequently than in earlier reviews and published behavioral intervention applications (Glasgow et al., 2004; Klesges et al., (2012); Klesges et al., 2005; Klesges et al.2008)
- 67% proposed to collect measures of representativeness of participants

# Variable Implementation continued

- 45% reported plans to assess adoption at the delivery staff level with the 31% reported assessments of percentage of potential staff participating
- Most applications 85% had measures of implementation fidelity (85%); 45% proposed measures of intervention adaptation (and 59% planned cost assessment
- 59% of proposals specified plans to assess items of long-term maintenance ( $\geq 6$  months follow-up) at the individual level.
- 73% included measures of maintenance at the setting (73%) level and 59% at the individual level



# Common misinterpretations of RE-AIM

- Confusion between **reach**- the *individual* citizen, consumer or patient level- and **adoption**- participation and representativeness at multiple *setting and staff levels*.
- **Guidance** on calculating reach: divide the number of persons beginning a program by the eligible participants in target to determine **Percent Participation or Reach**.
- Incorrect denominator in calculating percentages of individual and setting level participation by using only respondents rather than target population as the denominator.



## Example

If an email was sent to 200 County health departments about a new CQI program and how they could adopt this program and 50 participated in an informational phone call to get more information, and 20 actually begin participation in the program, the Adoption calculation would be  $20/200$ , not  $20/50$ .

# Key Issues

- The key issues for both errors -Denominator should reflect all approached and considered for participation, at both the individual (**Reach**) and setting (**Adoption**) levels
- Important to also determine representativeness of participants (**Reach**) and the adopters (**Adoption**) by comparing demographics and other relevant variables by participants and nonparticipants
- Report common reasons for declining participation

# Emerging issues related to more sophisticated or advanced uses of RE-AIM

- Data on representativeness and reasons for participation/nonparticipation at both the individual (**reach**) and setting (**adoption**) levels
- Use of mixed methods to understand implementation issues
- Combining scores or results on multiple dimensions to provide estimates of overall impact
- Increased study of relationships among outcomes on different RE-AIM dimensions
- Transparent reporting on all items, especially adaptations made during evaluation, and unintended consequences.

# What does it mean to use the RE-AIM framework?

- Standardized reporting on multiple RE-AIM dimensions
- Not all grant questions may be appropriate for inclusion of all RE-AIM dimensions.
- If full RE-AIM model use of proposed items and criteria isn't possible, it is reasonable to employ two or three RE-AIM dimensions
- Stated clearly and justified, rather than claiming to employ the entire model.
- RE-AIM is a dynamic construct. We welcome feedback on the recommendations for fully developed use
- Consider use of a brief table summarizing the specific definitions and measures of each of the key components

# An evolving trend to use RE-AIM at earlier stages of program and policy planning

- Earliest applications of RE-AIM retrospective evaluations and reports on intervention outcomes; initial RE-AIM reviews focused on literature review and synthesis (Gaglio & Glasgow, 2012 (in press); Glasgow et al., 1999; Glasgow, Bull, Gillette, Klesges, & Dzewaltowski, 2002)
- We endorse more recent applications emphasizing use of RE-AIM for planning and comparing different intervention and policy alternatives (e.g., (Jilcott et al., 2007; King et al., 2010; Klesges et al., 2005)

**If RE-AIM is to be regarded as a meaningful yardstick for evaluating interventions, then a standard definition of meaningful use of the framework is required**

- If “anything” it loses meaning, but if “you have to do everything to have a practical account as RE-AIM” then the framework loses application and local adaptation
- Some studies more amenable to the use of some RE-AIM dimensions and items than others
- “Fully developed” typically is defined by choices (e.g., 3 out of 4 criteria)

# Limitations

- We evaluated only one type of grant application mechanism to NIH
- We are proposing new criteria
  - Some criteria are in publication, we present them as an opportunity to advance the field and the model
- Cannot suggest the extent to which our findings apply to other evaluation or implementation science models
- Multiple coders for the grant data with good reliability, to create a consensus-based definition for genuine use of the RE-AIM model
- As frequent users of RE-AIM, thinking has changed over time that will discuss in future presentations



# Conclusion

- Whether using RE-AIM or other models, evaluation and implementation science should evaluate outcomes broadly and assess results from multiple stakeholder perspectives (Kessler & Glasgow, 2011; Treweek & Zwarenstein, 2009)
- Including costs and economic outcomes is crucial
- Need to address the relationships among different dimensions, evaluate impact on health disparities, employ mixed methods approaches, and assess unanticipated consequences, both negative and positive
- Frameworks for evaluating models need to be clear about what counts as a genuine application of the model, while allowing room for local adaptation of the framework



# Discussion and Questions

